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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,494	06/05/2001	Tseng-hui Timothy Chen	COUL-012/01US	7143

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,494

Applicant(s)

CHEN ET AL.

Examiner

David Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, 28 and 29, drawn to an isolated polynucleotide sequence comprising a leader sequence, ribosome binding sequence, recombinatorial sequence, etc., and vectors comprised of said sequence, classified in class 536, subclass 22.1.
Claim 4 is claimed in a Markush type format; however all of the members of the group do not possess unity of invention and instead are potentially distinct inventions recited in the alternative. The members of the group are different and patentably distinct from each other because the members are different molecules where there is no functional relationship between all of the members of the group (See MPEP 803.02). Upon election of Group I, applicant is required to elect from the members of the group set forth in the claim as follows: either a hormone (includes insulin), an interferon, or an immunoglobulin (includes an immunoadhesin) must be elected.
- II. Claims 25-27, drawn to a fusion polypeptide, classified in class 530, subclass 300 and 350.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claims 11, 13 and 27 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide or amino acid sequences to

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be claimed in a single application. Under this policy, a single independent and distinct nucleotide or amino acid sequence will be examined in a single application.

Claims 11 and 27 specifically claim amino acid SEQ ID NOS: 1-4 and 23. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique amino acid sequence representing a distinct polypeptide. Furthermore, a search of more than one (1) of the sequences claimed in claims 11 and 27 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one (1) sequence when electing Group II as set forth above. Although applicant claims these sequences in Group I as well, the sequences are amino acid sequences, and the invention of Group I is a polynucleotide, therefore the sequences do not read on the invention.

Claim 13 specifically claims nucleotide SEQ ID NOS: 5-8. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence has a unique nucleotide sequence and encodes a distinct polypeptide. Furthermore, a search of more than one (1) of the sequences claimed in claim 13 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect one (1) sequence when electing Group I as set forth above.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. A polynucleotide and a polypeptide have different sequences and structures, therefore they have different functions. A search of one group would not be coextensive with a search of the other hence said search would be burdensome.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
September 27, 2002

DAVID GUZO
PRIMARY EXAMINER
